PSJ9 Exh 56



State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 (614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License

Prescription Supply, Inc.

2233 Tracy Road Northwood, OH 43619 Wood County

Wholesaler/Manufacturer
Category Three
Wholesale Distributor Inspection

October 20, 2017

Written Response Required

Printed: 10/20/2017 3:49 AM Page: 1 of 5

License - Prescription Supply, Inc.

Page: 2 of 5

Written Response Required Details

23) Wholesale Facilities

9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Phar...

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License - Prescription Supply, Inc.

License

- Prescription Supply, Inc.

Full

Page: 3 of 5

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 (614) 466-4143 | Fax (614) 752-4836

Completed by Kevin E. Flaharty Start 10/20/2017 3:18 AM End 10/20/2017 3:49 AM

http://www.pharmacy.ohio.gov

Organization

Name Prescription Supply, Inc.

License Type Wholesaler/Manufacturer

Category Category Three

License Number

Business Type Full Service

DEA Number

Responsible Person

Jacquelyn J. Harbauer

Hours of Operation

Contact

Address 2233 Tracy Road Northwood, OH 43619 **Wood County**

Primary Number (419) 661-6600

Fax Number (419) 661-6617 Website

Personnel

Name **Initials Position** I.D. No. Phone **Email** Jacquelyn J. Harbauer Responsible (419) 661-6600 jharbauer@prescriptionsupply.com Person Thomas G. Shoen Manager (419) 661-6600 x tschoen@prescriptionsupply.com 118

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License - Prescription Supply, Inc.

Page: 4 of 5

23) Wholesale Facilities

* 9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Pharmacy. Written Response Required

No

Observation

Observation 1:

An inspection was performed by Agents with the Ohio State Board of Pharmacy on May 22, 2017. During that inspection, Agents asked a prescription Supply representative for their policies and procedures on reporting suspicious orders to the Ohio State Board of Pharmacy. Prescription Supply provided the Agents the following: Suspicious Order Monitoring Statement and Retail Pharmacy Questionnaire 2016.

However, Prescription Supply has not reported a suspicious drug order to the Ohio State Board of pharmacy during at least the years of 2014, 2015, 2016, and 2017. Therefore, it appears that Prescription Supply does not have a suspicious order reporting process compliant with rule 4729-9-16 (H)(1)(e)(i), which states, in part:

- (H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.
- (1) These records shall include, but shall not be limited to, the following information:
- (e) A system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.
- (i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

Warning with Required Written Response for:

- 1. Explain in detail how your policies and procedures for identifying and reporting suspicious orders meet the requirements of rule 4729-9-16(H).
- 2. Explain in detail why there have been no suspicious orders reported to the Board for years 2014, 2015, 2016, and 2017.

Observation 2:

A subsequent review of wholesale sale data reported to the Ohio State Board of Pharmacy for drugs containing Oxycodone 10mg and Oxycodone 30mg indicated many sales appeared to be of unusual size, unusual frequency, or that deviate substantially from established buying patterns, but were not reported to the Board of Pharmacy as suspicious orders. Specifically, we observed spikes in sales for specific months and sales that seem to steadily increase or spike and then abruptly stop. See referenced sales in the attached spreadsheet.

Warning with Required Written Response for:

- Please explain the rationale for <u>EACH</u> of the monthly sales noted in attached spreadsheet, including but not limited to:
- Why did Prescription Supply determine it was not necessary to report any of the sales to the Board of Pharmacy as a suspicious order?
- For sales that steadily increase or spike and abruptly stop, please explain rationale for the stoppage.
- Explain why the instances of high volume sales identified in the attached spreadsheet, including those that increased over time, were not identified as suspicious orders.
- In the attached spreadsheet, where the Board has identified abrupt cessation of sales, did Prescription Supply refuse to continue selling to the particular customer? If so, explain why including, but not limited to:
- · Was the cessation of sales due to you identifying the sale as a suspicious order?
- Did the customer cease sales on their own?
- Was there some other explanation for the stoppage?

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License - Prescription Supply, Inc.

Page: 5 of 5

33) Inspection Affirmation

1) Inspection Affirmation

Observation

This inspection report is being emailed to you to respond to items surrounding suspicious orders. Please note, that a written response is required from you within five (5) business days and should be sent to writtenresponse@pharmacy.ohio.gov with a copy of this inspection report. If you have any questions, please contact Agent David Gonzalez at (937) 538-0774 or by email at David.Gonzalez@pharmacy.ohio.gov

Summary

Written Response Required

Reviewed by Jacquelyn J. Harbauer	
	(signature)

Printed: 10/20/2017 3:49 AM Page: 5 of 5

Prescription Supply Sales

Pharmacy	City	DEA#	Drug	Sale Comments (Month-Year and numbers are dosage units)	
			Oxycodone 10mg	Spike 12-14 at 12,500	
			Oxycodone 30mg	Spike 4-14 at 5,400	
			Oxycodone 30mg	Spike 1-15 at 5,100	
	1		Oxycodone 10mg	Gradual increase in sales from 1-14 and then spike in 10-17 at 2,300, then sales abruptly stop	



State of Ohio Board of Pharmacy

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Written Response

License Prescription Supply, Inc.

2233 Tracy Road Northwood, OH 43619 Wood County

Wholesaler/Manufacturer
Category Three
Wholesale Distributor Inspection

October 25, 2017

License - Prescription Supply, Inc.

Written Response Required Details

23) Wholesale Facilities

9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Phar...



License

- Prescription Supply, Inc.

Full

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 (614) 466-4143 | Fax (614) 752-4836 http://www.pharmacy.ohio.gov

Completed by Kevin E. Flaharty Start 10/20/2017 3:18 AM End 10/20/2017 3:49 AM

Organization

Name

Prescription Supply, Inc.

License Type

Wholesaler/Manufacturer

Category Category Three

License Number

Business Type

Full Service

DEA Number

Responsible Jacquelyn J. Harbauer

Person

Hours of Operation

Primary Number

(419) 661-6600

Contact

Address

2233 Tracy Road

Northwood, OH 43619

Wood County

Fax Number

(419) 651-6617

Website

jharbauer@prescriptionsupply.com

tschoen@prescriptionsupply.com

Personnel

Name

Jacquelyn J. Harbauer

Position Responsible

I.D. No.

Phone (419) 661-6600

(419) 661-6600 x

Thomas G. Shoen

<u>Initials</u>

Person Manager

118

License - Prescription Supply, Inc.

23) Wholesale Facilities

* 9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Pharmacy. Written Response Required

No

Observation

Observation 1:

An inspection was performed by Agents with the Ohio State Board of Pharmacy on May 22, 2017. During that inspection, Agents asked a Prescription Supply representative for their policies and procedures on reporting suspicious orders to the Ohio State Board of Pharmacy. Prescription Supply provided the Agents the following: Suspicious Order Monitoring Statement and Retail Pharmacy Questionnaire 2016.

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(I) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

Warning with Required Written Response for:

Explain in detail how your policies and procedures for identifying and reporting suspicious orders
meet the requirements of rule 4729-9-16(H).



 Explain in detail why there have been no suspicious orders reported to the Board for years 2014, 2015, 2016, and 2017.

RESPONSE: We have not had any suspicious orders as we have received prior justifications/explanations for quantity changes/spikes/terminations.

Observation 2:

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License

- Prescription Supply, Inc.

A subsequent review of wholesale sale data reported to the Ohio State Board of Pharmacy for drugs containing Oxycodone 10mg and Oxycodone 30mg indicated many sales appeared to be of unusual size, unusual frequency, or that deviate substantially from established buying patterns, but were not reported to the Board of Pharmacy as suspicious orders. Specifically, we observed spikes in sales for specific months and sales that seem to steadily increase or spike and then abruptly stop. See referenced sales in the attached spreadsheet.

Warning with Required Written Response for:

 Please explain the rationale for <u>EACH</u> of the monthly sales noted in attached spreadsheet, including but not limited to:

Why did Prescription Supply determine it was not necessary to report any of the sales to the Board of Pharmacy as a suspicious order?

For sales that steadily increase or spike and abruptly stop, please explain rationale for the stoppage.

Explain why the instances of high volume sales identified in the attached spreadsheet, including those that increased over time, were not identified as suspicious orders.

 In the attached spreadsheet, where the Board has identified abrupt cessation of sales, did Prescription Supply refuse to continue selling to the particular customer? If so, explain why including, but not limited to:

Was the cessation of sales due to you identifying the sale as a suspicious order? Did the customer cease sales on their own?
Was there some other explanation for the stoppage?

33) Inspection Affirmation

1) Inspection Affirmation

Observation

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If you have any questions, please contact Agent David Gonzalez at (937) 538-0774 or by email at David.Gonzalez@pharmacy.chio.gov

Summary

Written Response Required

Reviewed by Jacquelyn J. Harbauer

1

(Signature)

Prescription Supply Sales

Pharmacy	City	DEA#	Drug	Sale Comments (Month-Year and numbers are dosage units)

WRITTEN RESPONSES FOR EACH PHARMACY ARE BOLDED BELOW

1. Why did Prescription Supply determine it was not necessary to report any of the sales to the Board of Pharmacy as a suspicious order?

Pharmacy submitted reasons for increase due to increase in patients

2. For sales that steadily increase or spike and abruptly stop, please explain rationale for the stoppage.

Not Applicable

Explain why the instances of high volume sales identified in the attached spreadsheet, including those that increased over time, were not identified as suspicious orders.

Not suspicious as explanation provided prior to increase.

- 4. In the attached spreadsheet, where the Board has identified abrupt cessation of sales, did Prescription Supply refuse to continue selling to the particular customer? If so, explain why including, but not limited to:
 - a Was the cessation of sales due to you identifying the sale as a suspicious order?
 - b Did the customer cease sales on their own?
 - c Was there some other explanation for the stoppage?

Not Applicable

- 1. Why did Prescription Supply determine it was not necessary to report any of the sales to the Board of Pharmacy as a suspicious order? Pharmacy submitted reason for increase due to projected shortage as defined by manufacturer's representative and an increase in patients due to additional doctors moving into the building. (See attached
- 2. For sales that steadily increase or spike and abruptly stop, please explain rationale for the stoppage.

Not Applicable

3. Explain why the instances of high volume sales identified in the attached spreadsheet, including those that increased over time, were not identified as suspicious orders.

Not suspicious as explanation provided prior to increase.

- 4. In the attached spreadsheet, where the Board has identified abrupt cessation of sales, did Prescription Supply refuse to continue selling to the particular customer? If so, explain why including, but not limited to:
 - d Was the cessation of sales due to you identifying the sale as a suspicious order?
 - e Did the customer cease sales on their own?
 - f Was there some other explanation for the stoppage?

Not Applicable

- Why did Prescription Supply determine it was not necessary to report any of the sales to the Board of Pharmacy as a suspicious order? Pharmacy submitted reasons for increase due to shortage by its primary supplier, Cardinal Health. (See
- 2. For sales that steadily increase or spike and abruptly stop, please explain rationale for the stoppage.

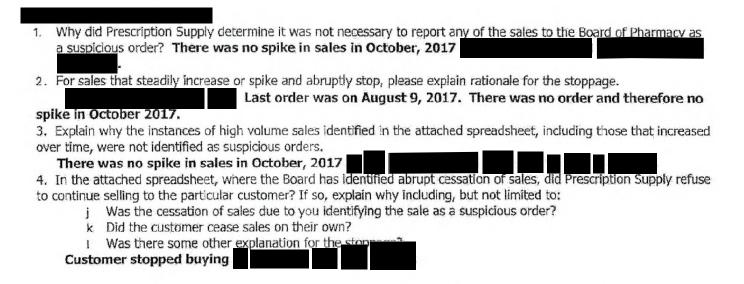
Not Applicable

3. Explain why the instances of high volume sales identified in the attached spreadsheet, including those that increased over time, were not identified as suspicious orders.

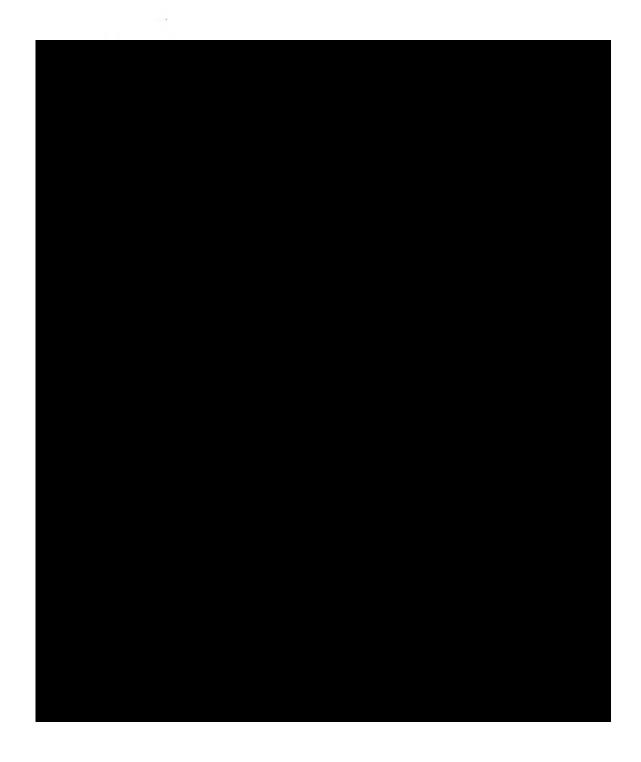
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 - g Was the cessation of sales due to you identifying the sale as a suspicious order?
 - h Did the customer cease sales on their own?
 - i Was there some other explanation for the stoppage?

Not Applicable



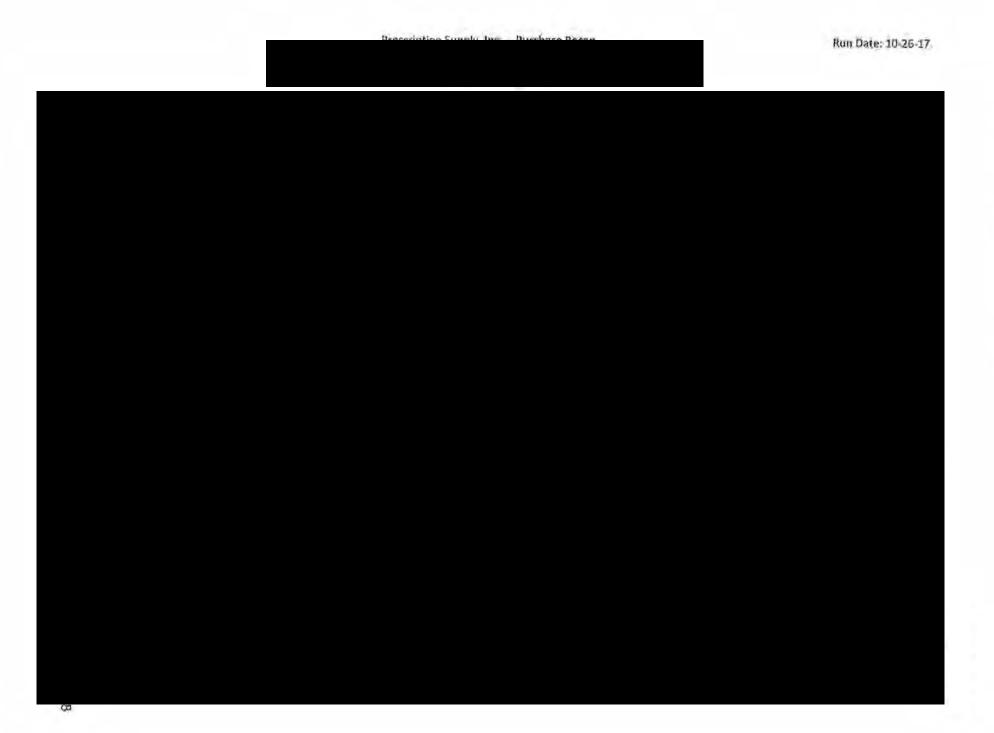
NOTE: On your data base, Thomas G. Schoen's name is misspelled. Also, Thomas is our President.



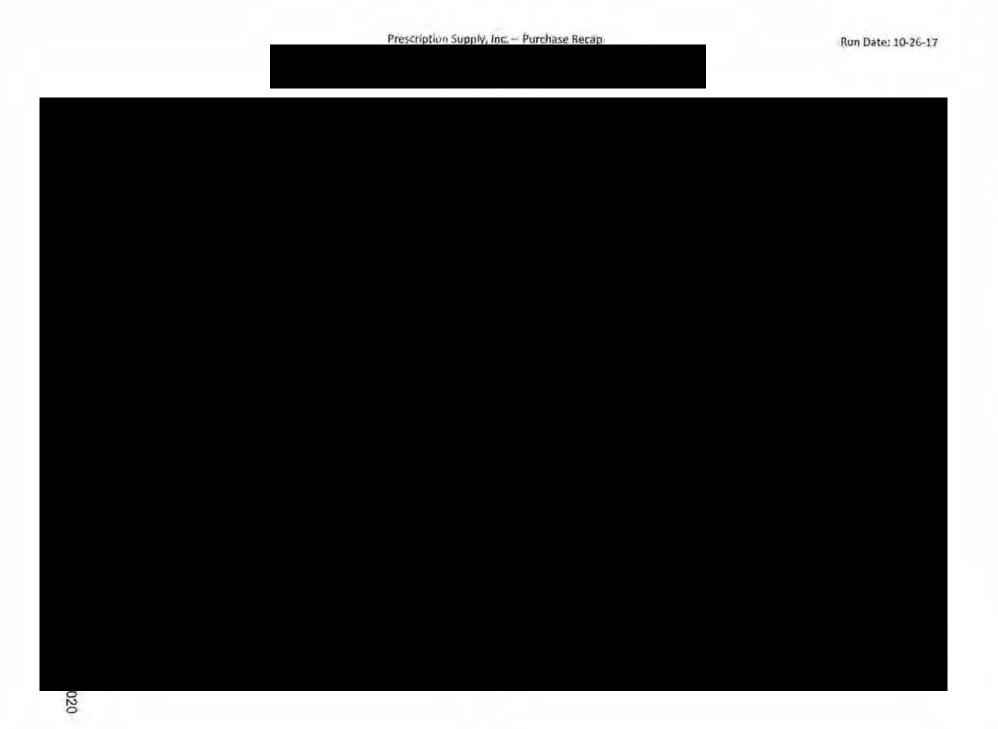
Prescription Supply, Inc. -- Purchase Recap



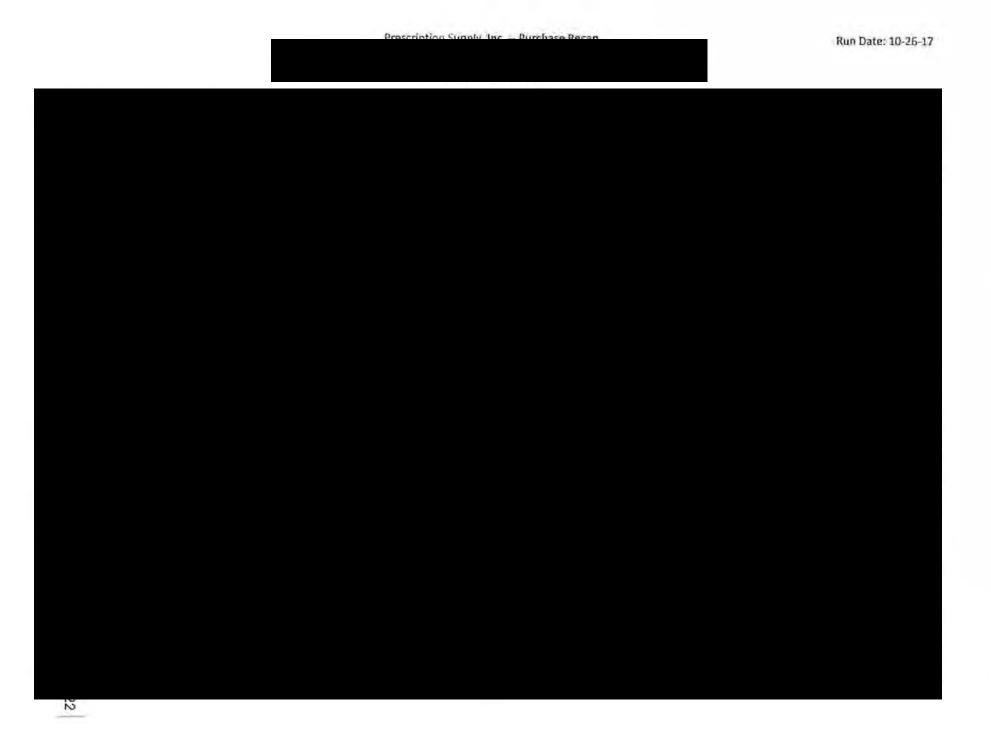
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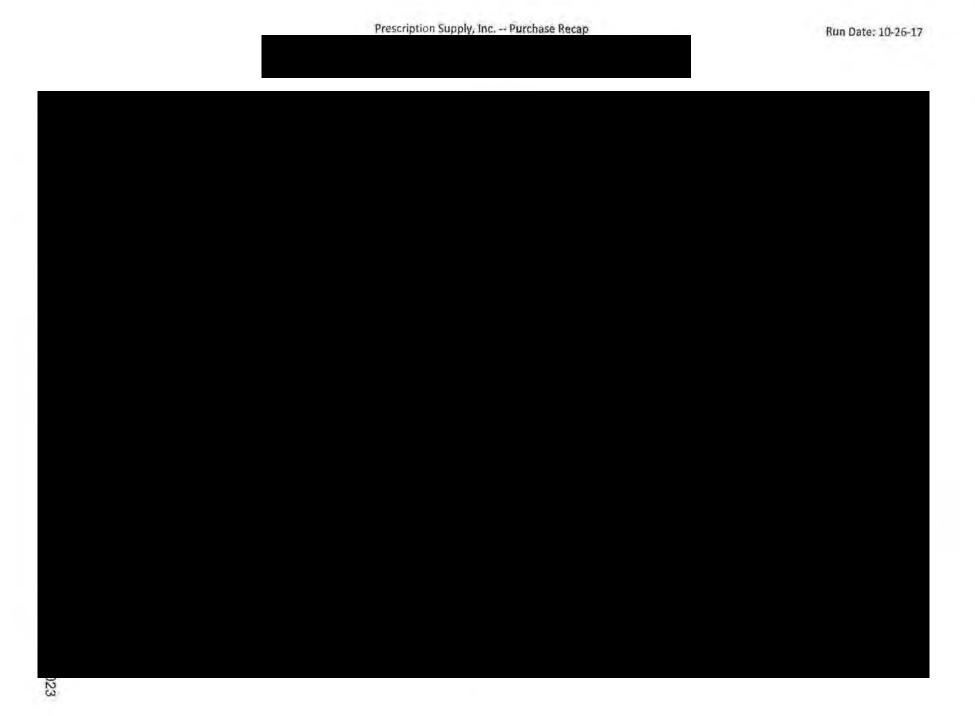


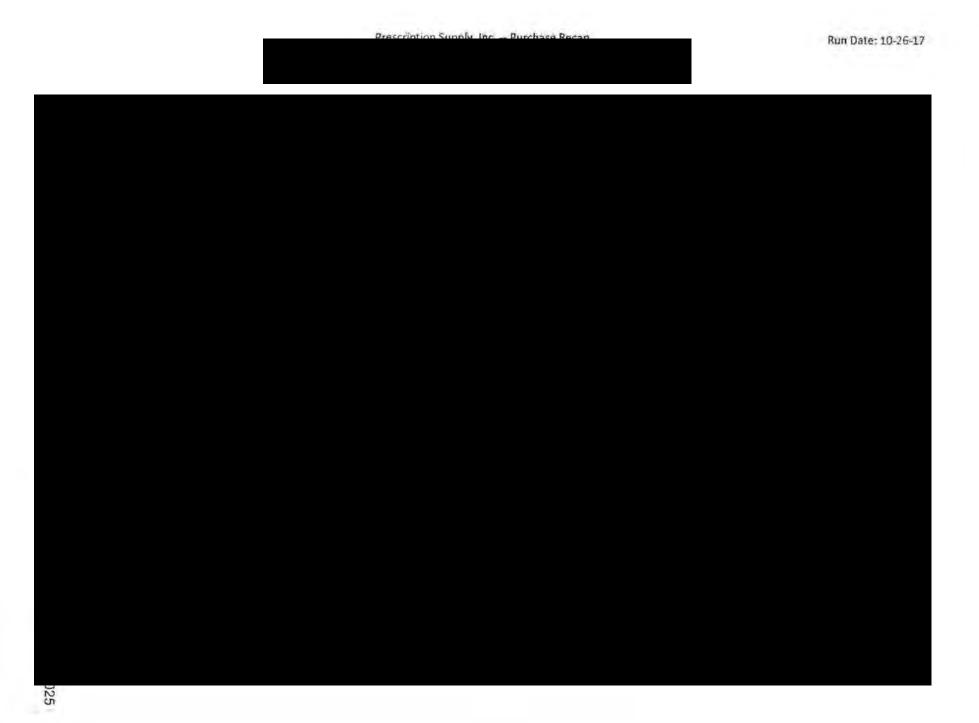
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Prescription Supply, Inc. - Purchase Recap Run Date: 10-26-17

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Prescription Supply, Inc. - Purchase Recap

Prescription Supply, Inc. - Purchase Recap

Prescription Supply, Inc. - Purchase Recap



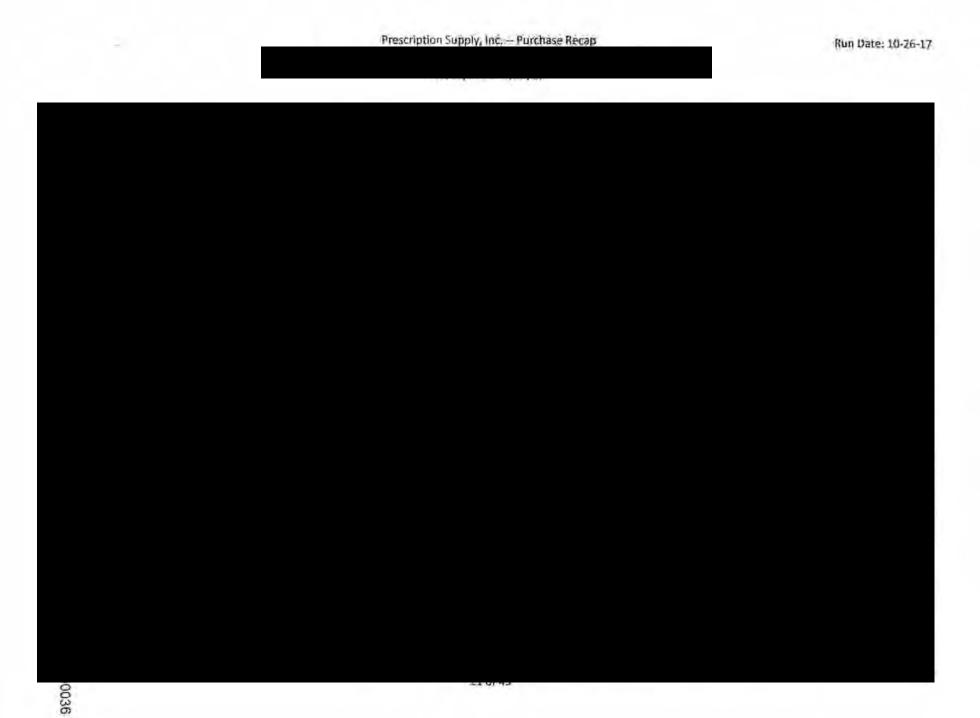
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Prescription Supply, Inc. — Purchase Recap



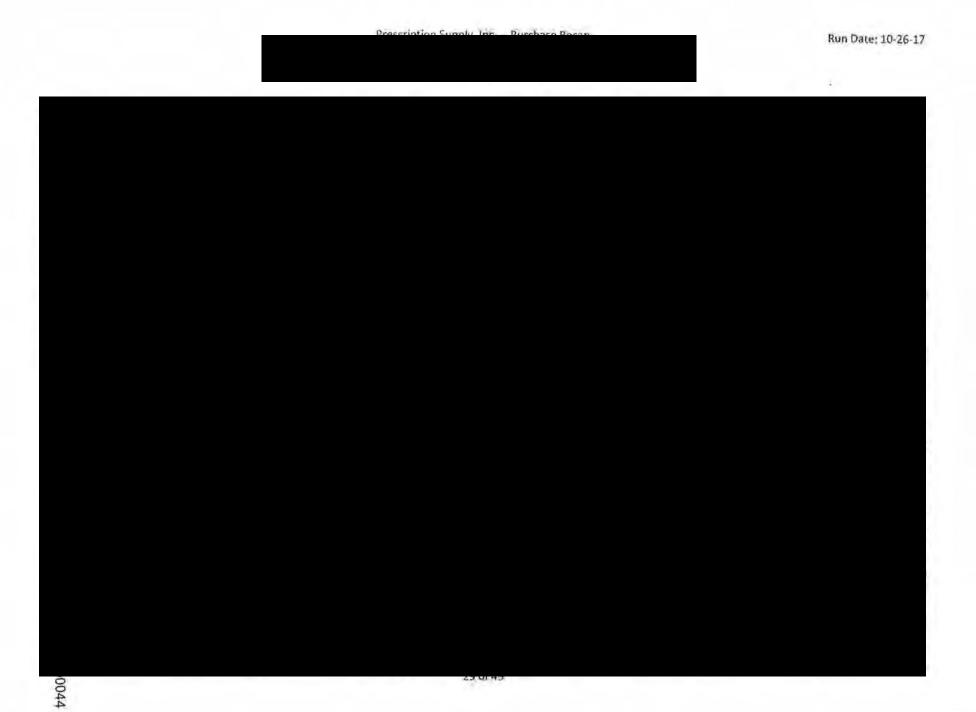
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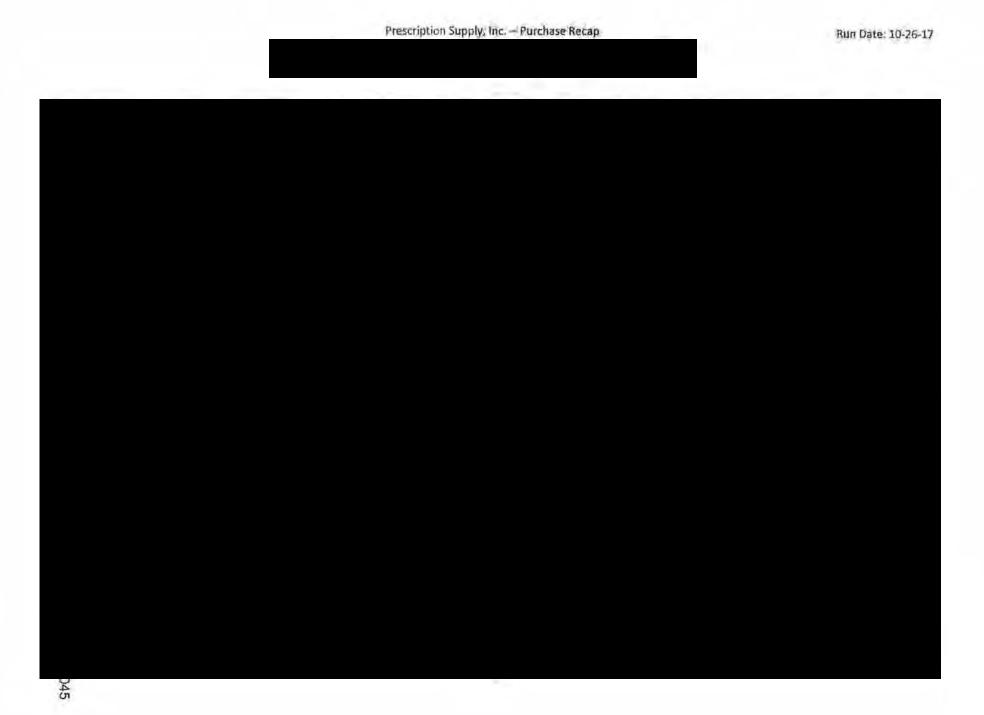
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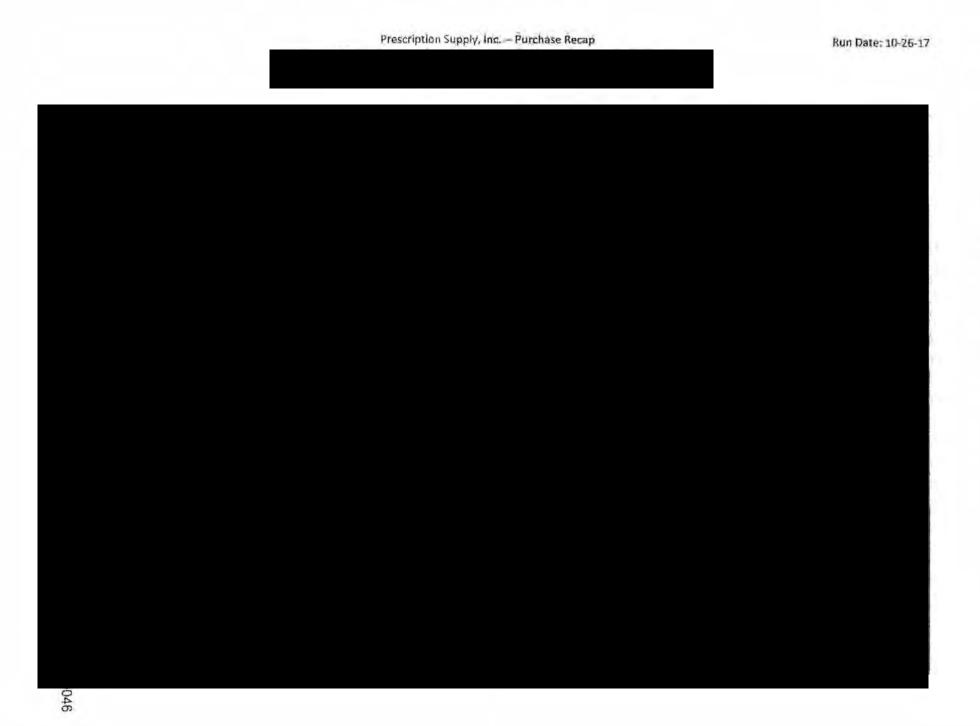
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Prescription Supply, Inc. - Purchase Recap Run Date: 10-26-17





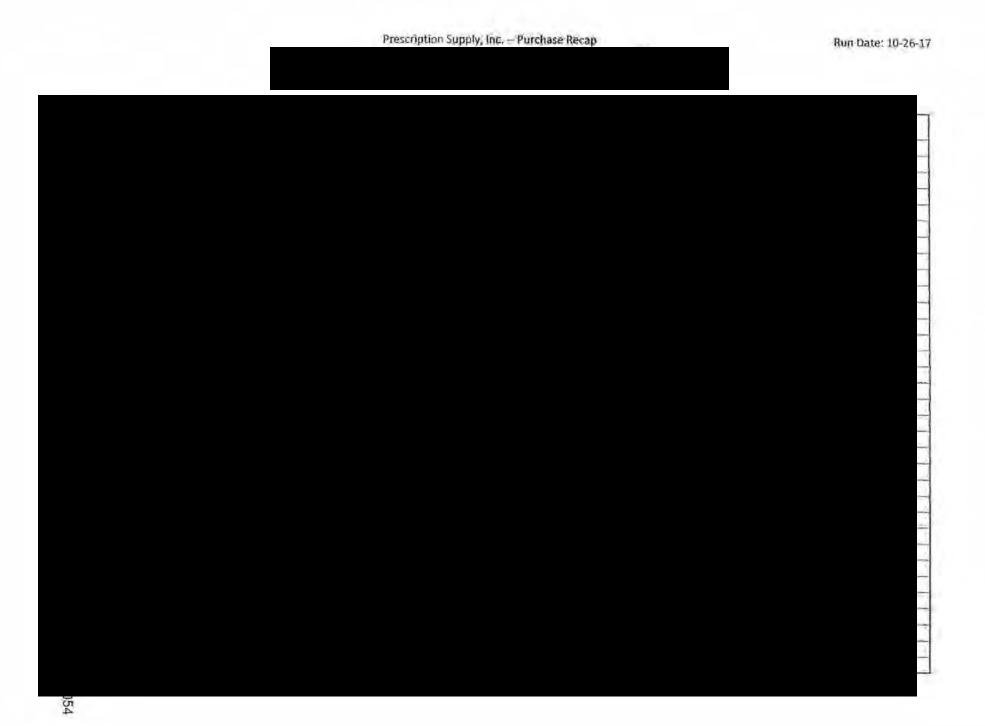


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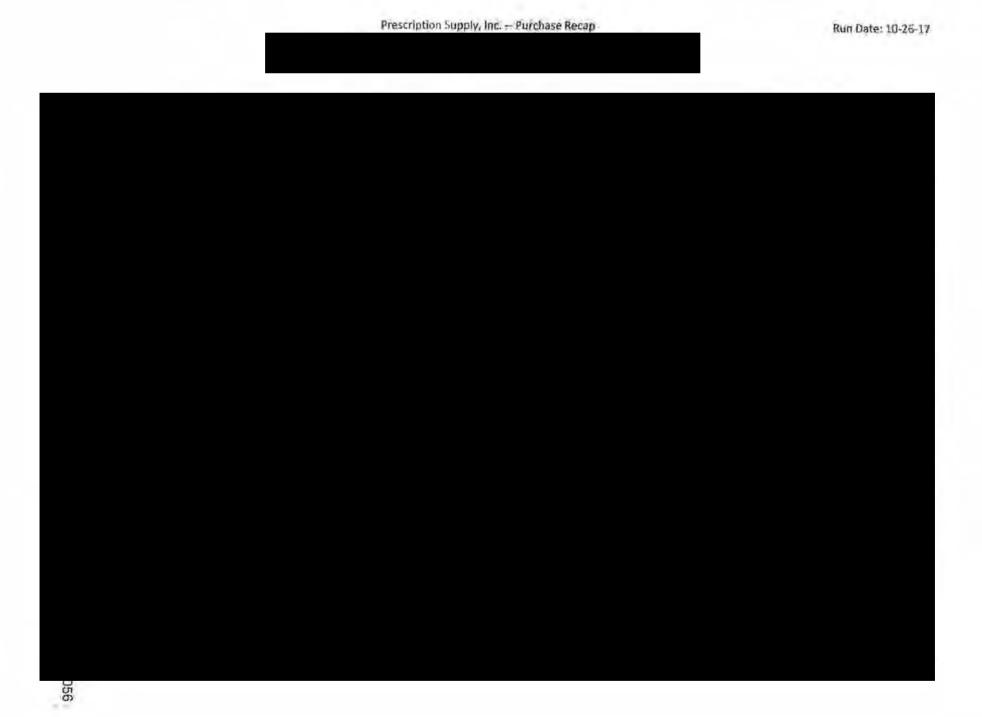
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Run Date: 10-26-17

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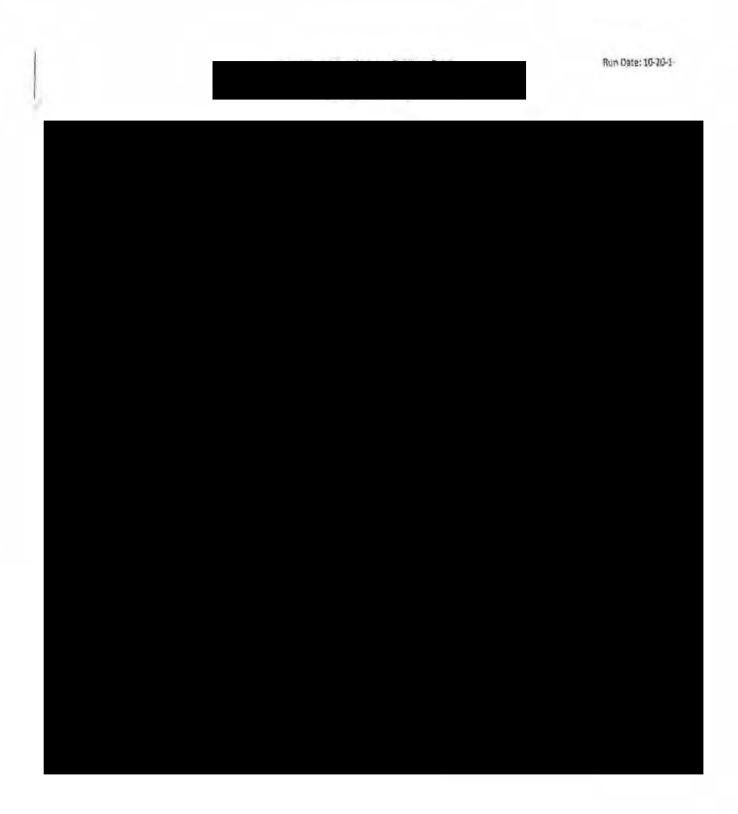
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Prescription Supply, Inc. - Purchase Recap-

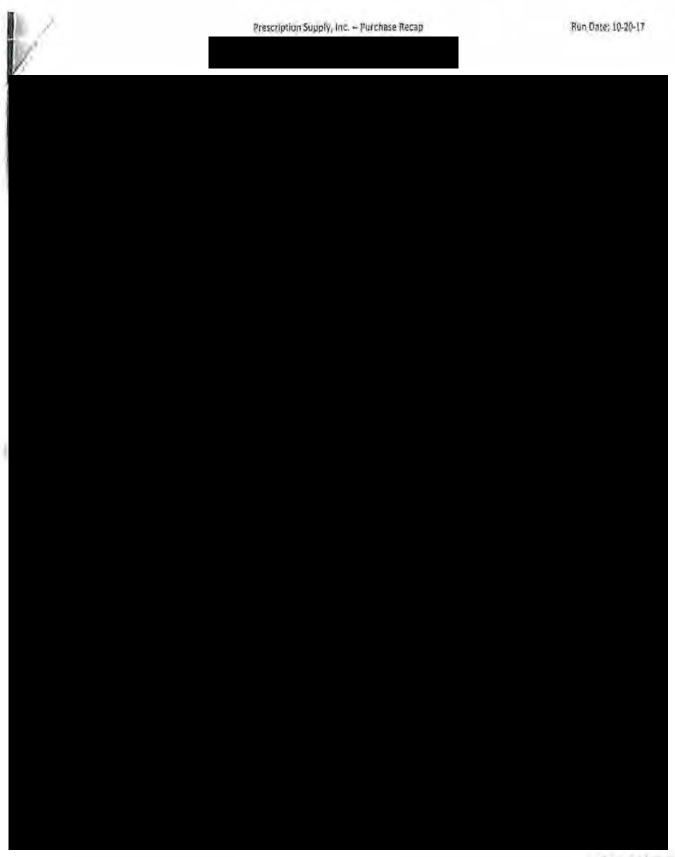
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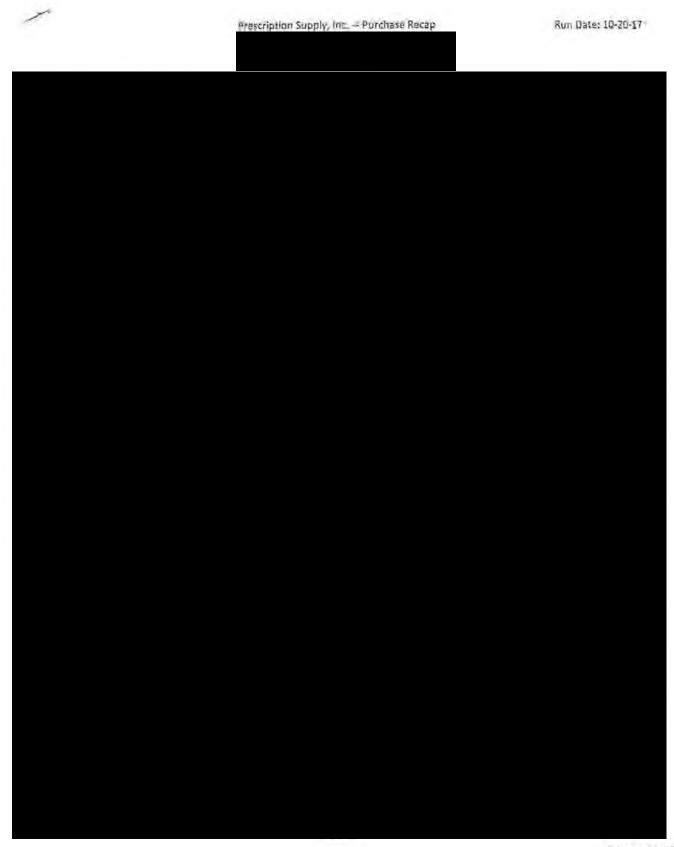


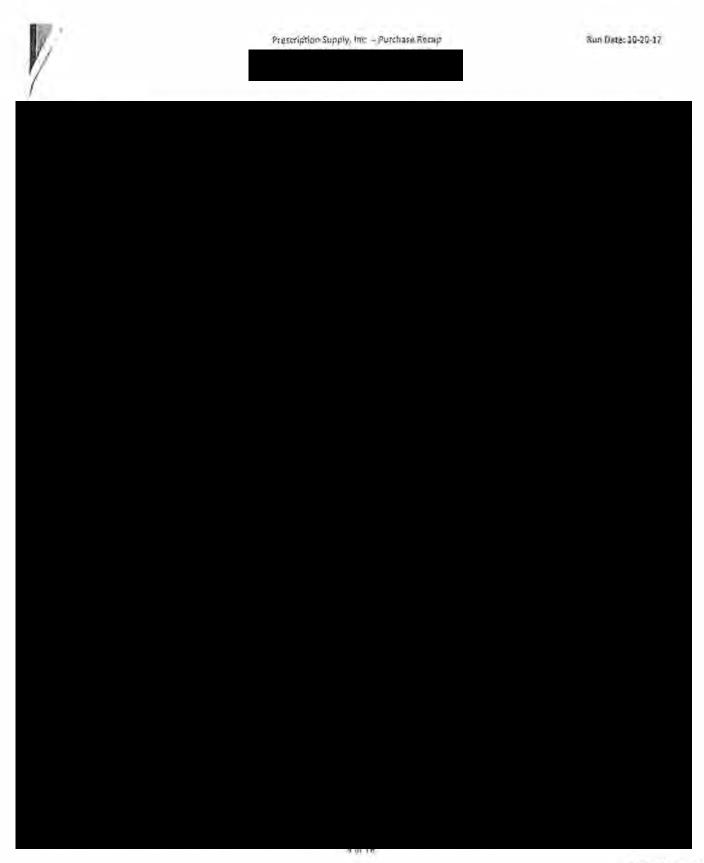


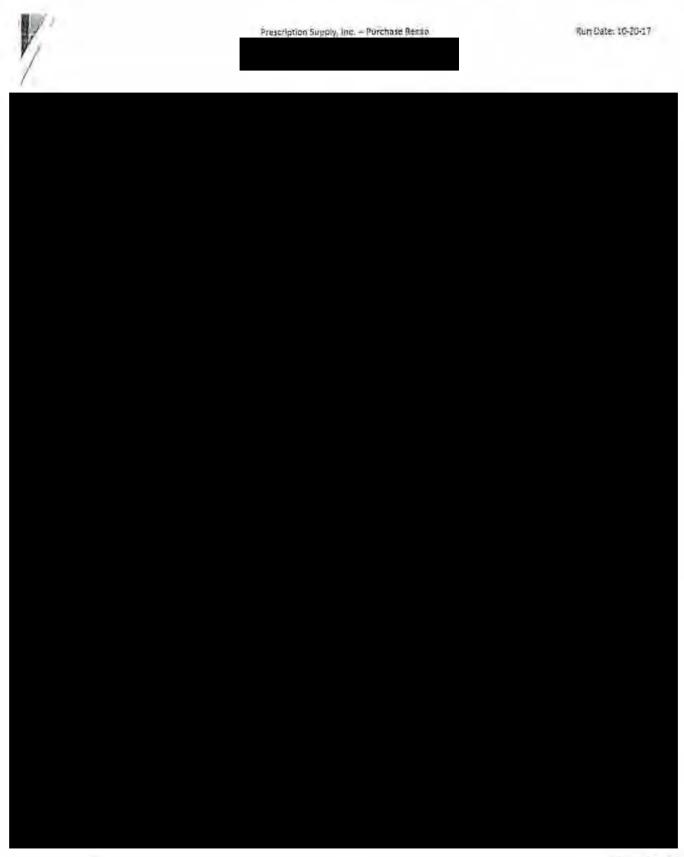


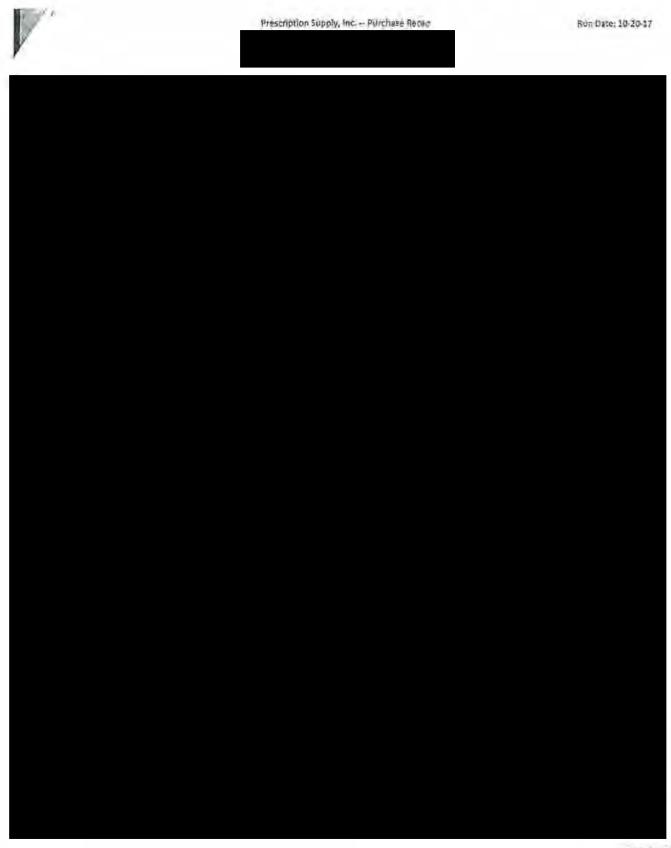


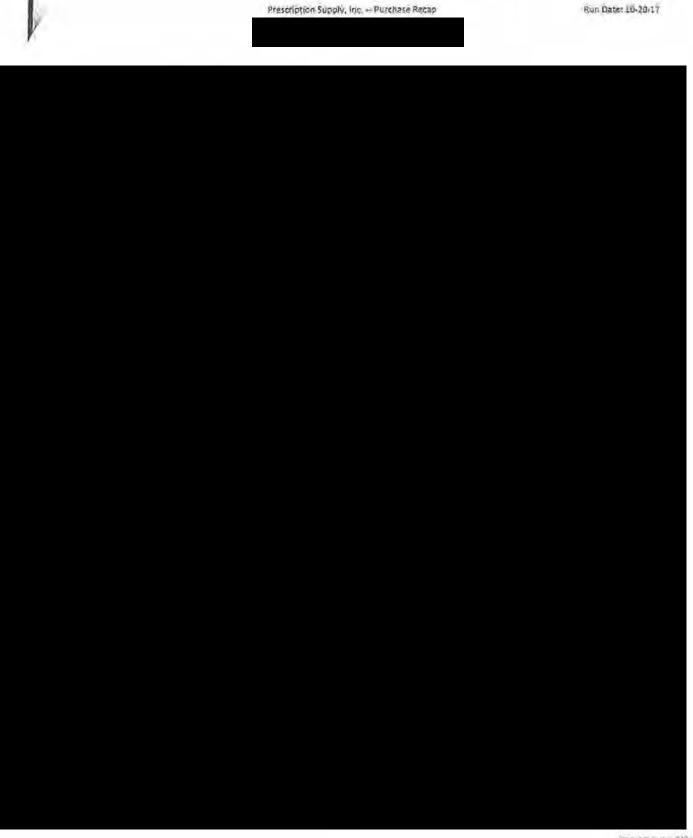
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U.S.	D	EPARTMENT OF JUSTICE	
DRUG EN	F	ORCEMENT ADMINISTRATION	

NOTICE OF INSPECTION OF CONTROLLED PREMISES

DEÀ USE OHLY FILE NUMBER

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NAME OF INDIVIDUAL -	3.3	THE ,		
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NAME OF CONTROLLED PREMISES PRESCRIPTION SUPPLY	Inc.	and the same of th		9
NUMBER AND STREET TO ACU ROS	<u>ا</u>		DATE 7/34/	02
CITY AND STATE NUTTHWOULD, ONIC	2 4	ZIP GODE 13619	TIME (initia) inspection	ર)
ST	ATEMENT OF	RIGHTS		***
 You have a constitutional right not to he administrative inspection warrant. You have the right to refuse to consent. Anything of an incriminating nature which a criminal prosecution. You shall be presented with a copy of the You may withdraw your consent at any 	to this inspection to this inspection to the total to the total this inspection of the total this inspection.	n. I may be seized pection.	and used against yo	ou in
ACKNOW	LEDGEMENT A	ND CONSENT		
James Schoen				Control State State College
Janus Inden		have been	advised of the above St	atement of Rights
DEA DIVERSION INVEST	igetor = f	maie +	Y ENCIS	who
(Title and Name)	0	0		
s identified himself herself to me with his/her credentials and 2(f) and 510(a). (b) and (c) of the Controlled Substances Adtherizing an inspection of the above—described controlled prodution, I hereby certify that I am the	of (21 U.S.C. 822(1) remises. I hazaby a STRCL SCE	and 21 U.S.C. 880	(a), (b) and (c), printed hold this Notice of Inspection MOILEGER	areon, *
or the premises described in this Notice of Inspection; that I is matter and have signed this Notice of Inspection pursuan		joing and understan	d its contents; that I have	e authority to act in
undersland what my rights are concerning inspection. No the against me. I voluntarily give consent for inspection of			me and no pressure of :	any kind has been
	per de le constitution de la con	*:		
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DEA Form June 1982) - 82 . Sae Reverse

U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

NOTICE OF INSPECTION OF CONTROLLED PREMISES

DEA USE ONLY FILE NUMBER

NAME OF INDIVIDUAL Jim Schoen!	TITLE	Clark
NAME OF CONTROLLED PREMISES PRESGRIPTION SUPPLY INC.		
NUMBER AND STREET 2233 TRACY ROAD		DATE 9-18-08
CITY AND STATE Northwood, Ohio	ZIP CODE 43519	TIME (initial inspection)

STATEMENT OF RIGHTS

- You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
 You have the right to refuse to consent to this inspection.
 Anything of an incriminating nature which may be found may be seized and used against you in
- a criminal prosecution.
 4. You shall be presented with a copy of this Notice of Inspection.
 5. You may withdraw your consent at any time during the course of the inspection.

ACKNOWLEDGMENT AND CONSENT

1:	Inn Si	LAGAL	, have been advised	of the above Statement of Rights
• • • • • • • • • • • • • • • • • • • •		(Name)		
by DEA	Diversion	Investigator Sand	a White-Hope	, wh
		(Title and Name)		
302(I) and authorizing	1 510(a), (b) and (d	 of the Controlled Substances the above-described controlled 	and presented me with this Notice of Inspection Act (21 U.S.C. 822(f) and 21 U.S.G. 880(a), (b) premises. I hereby acknowledge receipt of this	and (c), printed hereon, * Notice of Inspection. In
			(President) (Manager) (Owner)	
		in this Notice of Inspection; that this Notice of Inspection pursu	I have read the foregoing and understand its cor ant to my authority.	ntents; that I have authority to act in
		are concerning inspection. No ily give consent for inspection of	threats or promises have been made to me and fitness controlled premises.	no pressure of any kind has been
			A. T.	
			(Signature)	
			9-18-08	
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U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

NOTICE OF INSPECTION OF CONTROLLED PREMISES

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ILE NU	MBER		***************************************		

(Cate) (Paula Albert (Cate) (Cate) (Cate) (Cate) (Cate) (Cate) (Cate)	NAME OF INDIVIDUAL	TITL	**************************************	
DATE 233 Tracy Road Try AND STREET 233 Tracy Road Try AND STREET Rorthwood, Ohio STATEMENT OF RIGHTS 4. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant. 2. You have the right to refuse to consent to this inspection. 3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution. 4. You shall be presented with a copy of this Notice of Inspection. 5. You may withdraw your consent at any time during the course of the inspection. ACKNOWLEDGMENT AND CONSENT ACKNOWLEDGMENT AND CONSENT ACKNOWLEDGMENT AND CONSENT The DIVERSIGN Investigator Paula Albert Tribe and Name) Identified himseliblesself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections (1) and 310(a), (b) and (c) of the Centrolled Substances Act (21 U.S.C. 82(f) and 21 U.S.C. 80(a), (c) and (c), printed hereon, rorizing an inspection of the above described controlled presents. Thereby acknowledge receipt this Notice of Inspection in the above described controlled presents. Thereby acknowledge receipt this Notice of Inspection, in the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in matter and have a gived this Notice of Inspection, that I have read the foregoing and understand its contents; that I have authority to act in matter and have a gived this Notice of Inspection of these controlled premises. (Cate) TIMESSES: (Cate) (Cate)	IAME OF CONTROLLED PREMISES		IDE	A REGISTRATION NO.
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DEA Diversion Investigator Paula Albert , who (Title and Name) sidentified himselfherself to me with his/her credentials and presented me with this Notice of inspection containing a copy of sections ((i) and 510(a), (ii) and (ii) of the Centrolled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 86(a), (b) and (c), printed hereon, horizing an inspection of the above-described controlled premises. Hereby acknowledge receipt of this Notice of inspection. In filtion, I hereby certify that I am the			, have been adv	ised of the above Statement of Rights
sidentified himselftherself to me with histher credentials and presented me with this Notice of inspection containing a copy of sections 2(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c), printed hereon, horizing an inspection of the above-described controlled premises. Thereby acknowledge receipt of this Notice of inspection. In diction, I hereby certify that I am the		aula Albert		, who
the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in matter and have signed this Notice of Inspection. No threate and have signed this Notice of Inspection. No threate and have signed this Notice of Inspection. No threate and have signed this Notice of Inspection. No threate or promises have been made to me and no pressure of any kind has been against me. I voluntarity give consent for inspection of these controlled premises. TNESSES: [Date] [Date]	(Tilië and Name)		·	······································
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the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in matter and have signed this Notice of inspection pursuant to my authority. I have authority to act in matter and have signed this Notice of inspection. No threats or promises have been made to me and no pressure of any kind has been ad against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in pressure of any kind has been against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in pressure of any kind has been against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I voluntarily give consent for inspection of these controlled premises. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I have authority to act in premises have been made to me and no pressure of any kind has been against me. I have authority to act in premises have been me and no pressure of any kind has been against me. I have authority to act in premises have been me and no pressure of any kind has been against me. I have authority to act in premises have been me and no pressure of any kind has been against me. I have authority to act in premises have been me and no pressure of any kind has been against me. I have a large against me. I have a large agains	accinomical and a second a second and a second a second and a second a second and a second and a second and a		pert (Owner)	
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NOTIGE OF INSPECTION OF CONTROLLED PREMISES

DEA USE ONLY FILE NUMBER

NAME OF INDIVIDUAL	MILE	
NAME OF CONTROLLED PREMISES 4	V:1	DEA REGISTRATION NO.
Prescription Supply Inc		
NUMBER AND STREET		DATE
2233 Tracy Road		1-511-15
CITY AND STATE Northwood, OH	ZIP CODE 43619	TIME (initial interestion)
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ACKN	OWLEDGMENT AND CONSENT	
4	have be	en advised of the above Statement of Right
Christ Schollylone	1/	
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(Title and Name)		
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inderstand what my rights are concerning inspection. No ed against me. I voluntarily give consent for inspection of	threats or promises have been made to n	ne and no pressure of any kind has been
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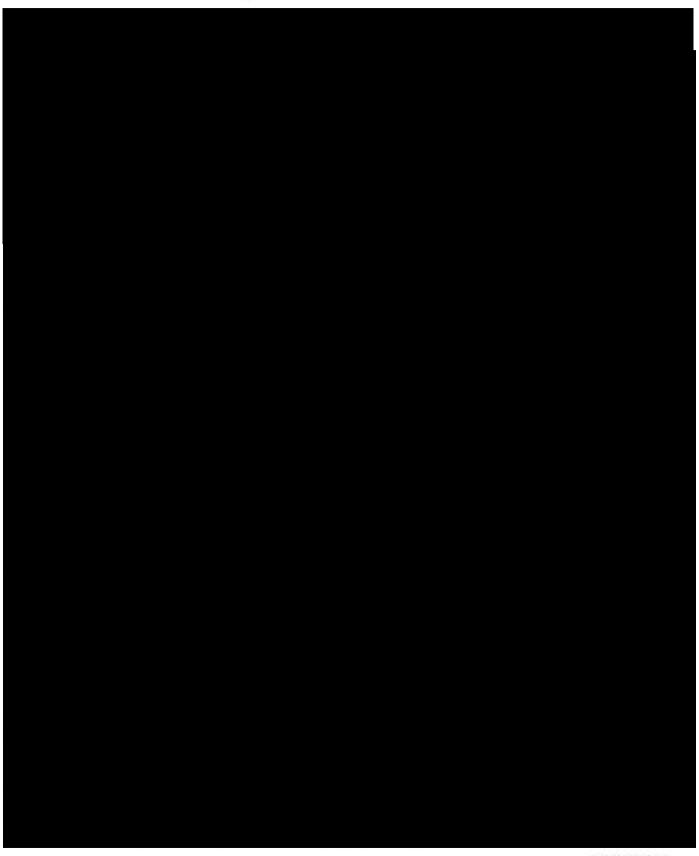
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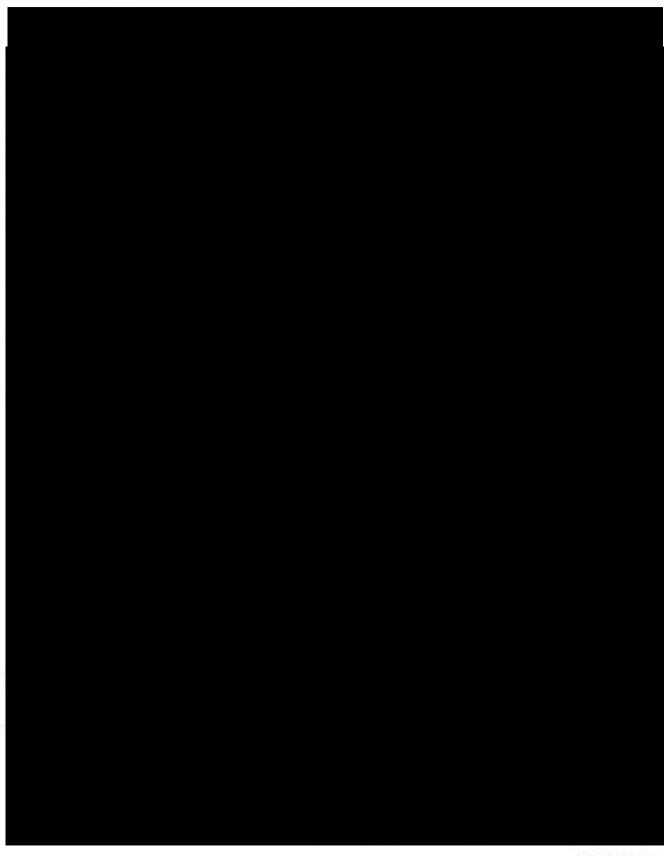
Prescription Supply Inc. Pharmaceutical Wholesale Distributor

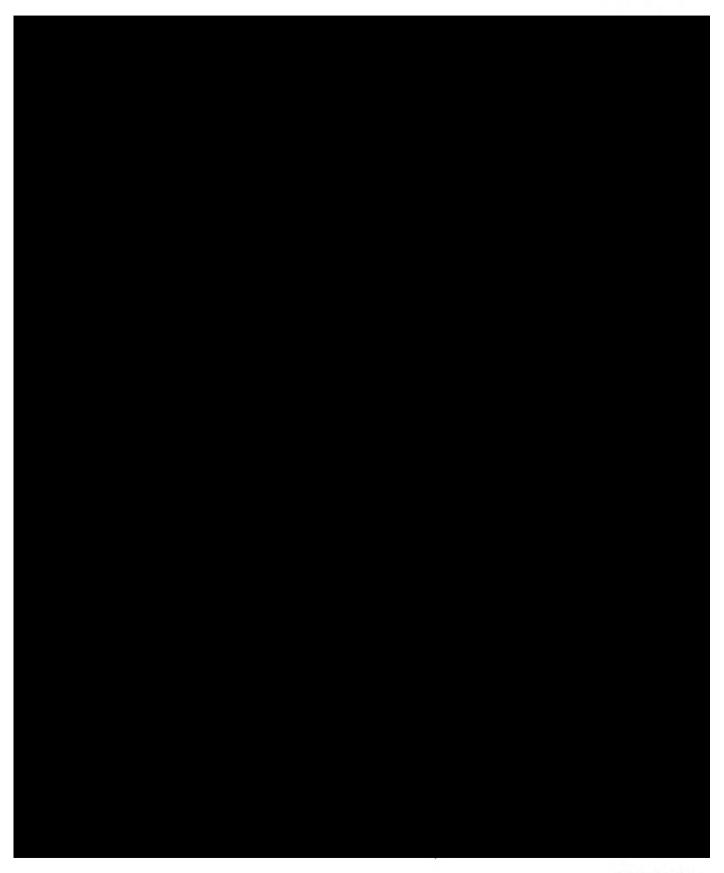
2233 Tracy Road Northwood, Ohio 43619

April, 2014





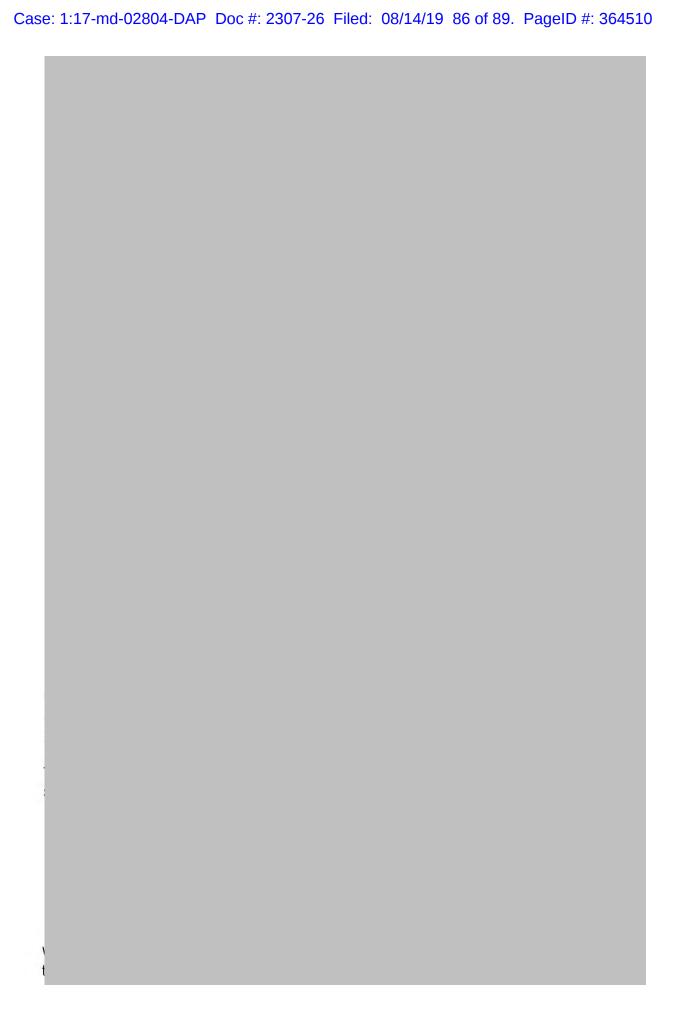






PRESCRIPTION SUPPLY, INC. 2233 TRACY ROAD NORTHWOOD, OH 43619

Document Name: INVENTORY CONTROLS	
Document Control Number: WP-1	



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